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10/568,176	11/30/2006	Howard J. Smith	P1119/20001	5589

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
03/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,176	SMITH, HOWARD J.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-43 are pending in the application.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: the present application does not contain a proper reference to priority U.S. provisional application 60/494828 in either the Application Data Sheet (ADS)or the first line of the specification. It is noted that, while the ADS of February 2006 does refer to the provisional application, it refers to it as a foreign priority application, and does not indicate that the present application (by way of the international application PCT/AU2004/001031) claims benefit of the U.S. provisional application.

Because the transmittal sheet recognized the claim for priority, not Petition for Delayed Claim of Priority is required.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on January 25, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

The Poynard et al. reference is in a foreign language. The reference has therefore not been considered beyond the information provided in the international search report.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 32 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6, 10, 14-22, 28-32, 35, 36, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 1-6, 10, 14-22, 28-32, 35, 36, and 43 is rejected for reference to “a low dose” of ribavirin. The term "low dose" in the claims is a relative term which renders the claims indefinite. The term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In addition, Claim 32 provides for the use of interferon in combination with ribavirin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

For the purposes of this action, claim 32 will be treated as reading on the method of claim 1.

Further, claim 35 recites the limitation "the low-dose of ribavirin" in line 1. There is insufficient antecedent basis for this limitation in the claim. The claim from which it depends, claim 33, makes no reference to such a dose of ribavirin.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4, 10, 14-25, 28, 32-35, 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganguly et al. (WO 00/23455- of record in the IDS of January 2007). These

claims are drawn to methods of treating a viral (esp. HCV) infection through the administration of an interferon-alpha (esp. interferon-alpha 2a or 2b) in combination with a low-dose and/or slow release formulation of ribavirin (including analogues thereof- page 9); or to kits or compositions comprising such a combination of interferon and ribavirin.

Ganguly teaches methods for the treatment of infection by hepatitis C virus (HCV) comprising the administration of interferon-alpha and ribavirin. In particular, the reference indicates that the interferon may be interferon-alpha 2a or 2b (pages 32-34, and claim 20), and various administration schedules thereof. The reference also teaches the co-administration of ribavirin. Page 34. Further, the reference teaches both compositions comprising these compounds, and methods for the treatment thereof. In teaching the compositions for administration according to the disclosed methods, the reference also teaches the compositions and kits of the present claims. The reference also indicates that the dosage may vary according to several factors, including the size (i.e. body weight) of the patient. Page 39. The reference also indicates that the compounds may be jointly administered for example by sustained related dosage (i.e. in a slow release formulation), or that the ribavirin may be administered orally in parallel to another mode of administration for the interferon. Pages 34-35. The reference also teaches compositions intended for use in such methods of administration, thus teaching the compositions and kits of the present claims. See e.g., abstract. The reference therefore anticipates the indicated claims.

10. Claims 1, 2, 10, 14-17, 18, 20, 32, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by McHutchison et al. (New Eng J Med 339:1435-92). These claims read on methods

for the treatment of viral infections comprising the administration of a therapeutically effective amount of interferon (esp. interferon alpha 2b) and a low dose of ribavirin. Because the application does not provide a definition for a "low dose of ribavirin," the term is read to include any amount of ribavirin that is lower than another dose of ribavirin.

McHutchison teaches the treatment of HCV through the administration of a combination of interferon alpha-2b and ribavirin. Page 1485. The reference teaches that, in certain cases, the dosage of ribavirin was reduced (hence a low dose of the drug was administered). Page 1489, right column, and page 1490, Table 5 (teaching administration of 600mg/day- approximately 8 mg/kg/day). The reference teaches the subcutaneous administration of the interferon at a dosage of 3 million units TIW, and oral administration of ribavirin. Page 1486. However, the reference does indicate that the dosages were adjusted depending on body weight. Id. Because the reference teaches the administration of the compositions, the reference inherently teaches the compositions themselves. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-4, 7-28, 32-35, 37-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ganguly et al. (supra). These claims are drawn to the methods and compositions described above, in particular where the claims

indicate that the low-dose of ribavirin may comprise between (e.g.) 5-399 mg/day or 1-5 mg/kg/day.

The teachings of Ganguly have been described in part above. Ganguly further teaches the co-administration of ribavirin, particularly in doses of 200-1600 or 400-800 mg/day or of above 1-30 or 4-15 mg/kg/day. Page 34. Because the ranges disclosed by the reference overlap with those of the present claims the teachings of the reference anticipate/ or render obvious, the claimed invention. See e.g., MPEP §§ 2131.03 II and 2144.05 I. The reference therefore anticipates, or renders obvious, the claimed inventions.

13. Claims 5, 6, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly as applied to claims 1-4, 7-28, 32-35, 37-43 above, and further in view of Wong et al. (U.S. 6,120,803). These claims are directed to the methods and kits described above, wherein the ribavirin is formulated as a slow-release tablet, such as those described by claim 6. As indicated above, Ganguly teaches that ribavirin may be administered through the use of a sustained (slow) release formulation, but does not teach the structure of such a formulation.

Wong teaches several forms of sustained release formulations that were known in the art at the time of invention of the presently claimed invention. See e.g., columns 3-4, and claim 1. It is noted that tablet, including polymer-coated and hydrophilic matrix tablets, are among the disclosed formulations. The reference indicates that such formulations are suitable for the delivery of a number of active agents, including ribavirin. See e.g., column 19. The reference teaches that erosion is a mechanism by which the slow release of the agent is achieved. Column 16, lines 14-19. In view of the these teachings, it would have been obvious to those of ordinary

skill in the art to have used such formulations for the delivery of the ribavirin disclosed in Ganguly. The combined teachings of the references therefore render the claimed inventions obvious.

14. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly as applied to claims 1-4, 7-28, 32-35, 37-43 above, and further in view of the teachings of Wong (supra) and Brass et al. (US 6849524). These claims are drawn to a method as described above, wherein an antioxidant is also administered, particularly wherein the antioxidant, such as Vitamin E or C (specification, page 9), is co-formulated in the slow-release formulation.

The teachings of Wong have been described in part above. It is noted that the reference also indicates that a combination of agents may be included in the described slow-release formulations. Column 20, lines 35-42. The reference also indicates that vitamins, such as Vitamin C, may be administered using such slow-release formulations. Column 17, lines 44-50. In addition, the teachings of Brass indicate that it was known in the art to co-administer Vitamins E and C with the combination treatment of interferon and ribavirin for the treatment of HCV for the purpose of ameliorating the hemolytic effects of ribavirin. See e.g., claim 1. It would therefore have been obvious to those of ordinary skill in the art to have co-formulated these vitamins with ribavirin in the slow-release formulations suggested by Ganguly and Wong. The combined teachings of these references therefore render the claimed invention obvious.

Conclusion

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

> Brass et al. (U.S. 6,849,254). This reference teaches the co-administration of interferon-alpha, ribavirin, and an antioxidant. The reference also indicates that the amount of ribavirin administered may require reduction (to a low dose of ribavirin). The reference is considered duplicative to those of the Ganguly and McHutchison references cited above with respect to the present claims.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648